HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

March 21, 2000

Dockets Management Branch
Mail Code HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 99N-4784: Proposed Rule: Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification

Dear Madam/Sir:

These comments are submitted by the Health Industry Manufacturers Association (HIMA) in response to the Food and Drug Administration's (FDA's) proposed regulation to establish requirements for sponsors to submit to FDA redacted versions of their 510(k)s within 30 days of their clearances. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the $159 billion purchased annually around the world.

General Comments

HIMA agrees with the overall purpose of the proposed rule, i.e., to provide holders of cleared 510(k)s improved opportunity to protect from disclosure nonpublic information contained in their 510(k)s while facilitating the lawful release of other information pursuant to specific provisions of the Federal Food, Drug, and Cosmetic Act (the Act) and the Freedom of Information Act (FOIA). Further, FDA notes that the proposed rule would benefit FDA by allowing the agency to redirect resources to product review and other activities. HIMA supports activities that would ultimately conserve the agency's resources and therefore, strongly urges FDA to direct resources savings from this proposed regulation to product reviews.

HIMA believes that FDA should address the specific concerns presented below before promulgating a final rule.

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Specific Comments

File Content Subject to Disclosure

> "Except for information that is exempt from disclosure under FOIA, all information in a 510(k) submission is available for disclosure to the public once the 510(k) is cleared. This includes the original submission, correspondence with FDA, memoranda of telephone conversations, amendments, or other supplemental information submitted prior to clearance of the 510(k) by FDA." (Section I.B, page 71348)

1. FDA should clarify that only information in FDA's files on the subject 510(k), except for information that is exempt from disclosure under FOIA, is available for disclosure to the public once the 510(k) is cleared. Specifically, FDA should clarify that the reference to memoranda of telephone conversations refers to such memoranda in FDA's files and does not include memoranda of telephone conversations that are retained only by the submitter, or any other information retained by the submitter that is not in FDA's files on the subject 510(k).

   "When a request is received for a particular 510(k) that has not been previously released under FOIA, FDA provides the 510(k) holder with a "predisclosure notification" in accordance with Executive Order 12600. Subject to certain exceptions, Executive Order 12600 requires the Government to notify submitters of records containing confidential commercial information prior to disclosure of those records in response to a FOIA request. The submitter is then permitted an opportunity to object to the disclosure of any part of the records and to state the basis for each such objection." (64 FR page 71348; December 21, 1999)

2. The proposed rule is deficient in that it does not provide the holder of a cleared 510(k) an opportunity to review for the purpose of redaction the entire FDA file that the agency believes is subject to FOIA disclosure. The entire file that is subject to the FOIA request includes the original submission, correspondence between the submitter and FDA, FDA memoranda of telephone conversations, amendments, or other supplemental information submitted prior to clearance of the 510(k) by FDA. Under the existing approach, when a 510(k) holder receives a predisclosure notification, the holder has an opportunity to review for purpose of redaction all these materials, as well as other FDA technical and administrative information documenting the review.

   FDA should continue to provide the 510(k) holder an opportunity to review for purpose of redaction all the material that presently is provided for redaction. This could be accomplished by FDA providing to the 510(k) submitter copies of the FDA memoranda of telephone conversations and other technical and administrative information documenting the review, as presently done, as attachments to the 510(k) clearance letter. This would provide the 510(k) holder an opportunity to redact this documentation at the same time the holder redacts information already in its possession (i.e., original submission,

correspondence with FDA, amendments, or other supplemental information submitted prior to clearance of the 510(k) by FDA). As an alternative to this approach, FDA could provide the rest of the redacted file to the sponsor at the time a request is made.

Scope, Structure, and Time Requirements of Proposed Rule

"The proposed rule would amend §807.87 (21 CFR 807.87) to require 510(k) applicants to include a statement that would commit the applicant to provide a redacted version of the 510(k) within 30 days of FDA's finding the device substantially equivalent." (64 FR page 71348; December 21, 1999)

3. FDA should clarify that the proposed rule applies to all types of 510(k)s, i.e., 510(k) following the traditional approach as well as "Special 510(k): Device Modification" and "Abbreviated 510(k)".

4. As an alternative to a required commitment to provide a redacted version of the 510(k) following its clearance, consideration should be given to requiring submission of redacted versions of the original and amendment 510(k) documents at the time of submission (as a content requirement). This would limit the effort, upon clearance, to reviewing for purpose of redaction only non-submission elements of the file presently disclosed under FOIA (e.g., FDA memoranda of telephone conversations, correspondence between FDA and the submitter, and other technical and administrative information documenting the review).

5. Under present circumstances, 30 days following FDA's finding a device substantially equivalent would not always be sufficient time for the submitter to provide a redacted version. There are occasional delays in submitters learning of the clearance of their 510(k)s. For example, there have been delays in FDA's Document Mail Center entering the clearance letters into the U.S. Postal Service and there have been delays by the U.S. Postal Service in delivering the mail (especially during holiday seasons). Therefore, FDA should lengthen the time for submission of the redacted version of the 510(k) to 45 days following FDA's finding and notification of substantial equivalence. Alternatively, FDA should commit to sending clearance letters to submitters by electronic means (e.g., by facsimile and/or e-mail) on the date of issuance concurrent with the hard copy mailing.

6. Although FDA states that the agency is required to respond to FOIA requests within 20 days, the proposed rule does not explicitly state the time limit that FDA would impose on itself for posting on the Internet a redacted 510(k) file after receipt. FDA should commit to posting redacted 510(k) files within a specified period of receipt.

Format of Redacted Versions and Copyright Issues

"FDA encourages, but would not require, the redacted version to be submitted on disk, preferably as a portable document format file (.pdf file)." (64 FR page 71349; December 21, 1999)

7. FDA should continue with its intent to encourage, but not to require, the redacted 510(k) file to be submitted on disk. The medical device industry consists of firms varying widely in size, infrastructure, and capabilities. Requiring the redacted version to be provided on a disk or other electronic format would impose an unreasonable burden on companies that lack the capability.

"The proposed rule does not address the redaction of 510(k)s submitted to FDA prior to the effective date of the regulation. FDA will continue to provide predisclosure notification for those documents under the existing approach for the 10 years following their date of submission to the agency, . . . , and will address redaction of these 510(k)s on a case-by-case basis using FDA's current approach." (64 FR page 71349; December 21, 1999)

8. FDA should devise an approach for posting on the Internet redacted 510(k) files that result from predisclosure notifications issued to holders of 510(k)s that had been submitted prior to the date of the regulation and that do not present the types of copyright infringement issues discussed by FDA in the proposal.

"Under the proposed rule, copyrighted materials whose copyright is owned by a person other than the applicant must be placed in a single appendix, . . . , and listed in a bibliography, . . . These copyrighted materials may not be included in any other portion of the 510(k). . . .FDA will not release the appendix containing copyrighted materials as part of a redacted 510(k) made available through FDA's Internet site, but would release the bibliography of the materials included in the appendix." (64 FR page 71350; December 21, 1999)

"Copyrighted materials whose copyright is owned by the applicant may be included, at the applicant's discretion, in any portion of a 510(k). FDA would treat these materials in the same manner as any other information submitted in a 510(k) and would include them in any redacted 510(k) made available through FDA's Internet site." (64 FR page 71350; December 21, 1999)

"§807.90(f). Include copies of copyrighted materials in a single appendix, which shall be the final section of the premarket notification. Copyrighted materials whose copyright is not owned by the applicant shall not be included in any other section of the premarket notification." (64 FR page 71353; December 21, 1999)

9. We support FDA's proposal to include all copyrighted material not owned by the applicant in an appendix that would not be made available in the redacted 510(k) file posted on the Internet.

10. We do not support one of FDA's alternative approaches whereby FDA could require from the 510(k) applicant explicit consent from each copyright holder to permit FDA to release the copyrighted materials through FDA's Internet site as part of the redacted 510(k) file. Obtaining such permission could be overly burdensome.

11. We recognize that some copyrighted materials whose copyright is owned by the submitter will have to be disclosed (e.g., owner's manual). We recommend that FDA explore the use of specialized software to resolve apparent dilemmas that may arise in providing FOIA disclosures via the Internet and in safeguarding against unlawful copyright infringement (e.g., software that provides random blocking circles, which do not appear when a document is viewed on line, but which obscure portions of the document when it is printed).FDA should also stipulate that when such owner's manuals are available for purchase from the sponsor, they are of commercial value and will not be made available through the FOIA process.

12. FDA should clarify an apparent discrepancy between the discussion of page 71350 and requirements proposed in §807.90(f). The discussion conveys that copyrighted materials whose copyright is owned by a person other than the applicant must be placed in a *single* appendix and that FDA will not release *the* appendix containing copyrighted materials as part of a redacted 510(k) made available through FDA's Internet site. This discussion also conveys that the 510(k) would contain a bibliography of these copyrighted materials placed in the appendix and FDA would release the bibliography as part of the redacted 510(k) file posted on the Internet. This implies that all such materials whose copyright is owned by persons other than the applicant would be referenced in the 510(k) but would be isolated from the remainder of the 510(k) and would not be disclosed (released) as part of the redacted 510(k) file posted on the Internet. Further, this implies that the copyrighted materials whose copyright is owned by a person other than the applicant would not be co-mingled with copyrighted materials whose copyright is owned by the applicant.

    However, proposed §807.90(f) would require including any [all] copies of copyrighted materials in a single appendix. As stated, the proposed regulation would not limit the appendix to just those materials whose copyright is not owned by the 510(k) applicant, but would include other copyrighted material as well. The proposed regulation goes on to specify that copyrighted materials whose copyright is not owned by the applicant shall not be included in any other section of the premarket notification. This latter provision reinforces the confusion, by implying that the appendix could include copyrighted materials of various ownership.

Relation to Requirement for a 510(k) summary or 510(k) statement

13. Section 513 (i) (3) of the Act requires an applicant to submit either a 510(k) summary or a 510(k) statement and the proposed regulation requires the applicant to submit a redacted 510(k). The proposed content requirement for a commitment to submit a redacted 510(k) file is the same information that the sponsor must provide to requestors when the sponsor chooses the 510(k) statement. The relationship between the redacted 510(k) and the sponsor's requirement to choose the option of submitting the 510(k) statement or 510(k) summary remains unclear. Although the agency attempts to explain the relationship in the supplementary information provided in the notice, HIMA recommends that the agency clarify the redundant role of the 510(k) statement or 510(k) summary and the requirement under this proposal to submit the redacted 510(k).

HIMA appreciates the opportunity to submit these comments.

Respectfully submitted,

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